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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CHIESI USA INC. and CHIESI FARMACEUTICI S.P.A.	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
GLAND PHARMA LTD.,	)	*Document Filed Electronically*
Defendant.	)	

COMPLAINT

Plaintiffs Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. (collectively, "Chiesi" or "Plaintiffs") by its undersigned attorneys, for its Complaint against Defendant Gland Pharma Ltd. ("Gland" or "Defendant") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 6,130,208 ("the '208 patent") (attached as Exhibit A herto), U.S. Patent No. 8,680,052 ("the '052 patent") (attached as Exhibit B hereto), U.S. Patent No. 9,427,448 ("the '448 patent") (attached as Exhibit C hereto), U.S. Patent No. 9,439,921 ("the '921 patent") (attached as Exhibit D hereto), U.S. Patent No. 9,700,575 ("the '575 patent") (attached as Exhibit E hereto), U.S. Patent No. 9,925,265 ("the '265 patent") (attached as Exhibit F hereto), and U.S. Patent No. 10,039,780 ("the '780 patent") (attached as Exhibit G hereto) (collectively, the "patents in suit").

THE PARTIES

2. Chiesi USA Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 175 Regency Woods Place, Suite 600, Cary, North Carolina 27518. Chiesi USA Inc. is a wholly owned subsidiary of Chiesi Farmaceutici S.p.A.

3. Chiesi USA Inc. is the owner of New Drug Application (NDA) No. 204958, which was approved by the U.S. Food and Drug Administration (FDA) for the manufacture and sale of Kengreal® (cangrelor) for injection.

4. Chiesi Farmaceutici S.p.A. is a corporation organized and existing under the laws of Italy, having a principal place of business at Via Palermo, 26 A, 43122 Parma, Italy.

5. Chiesi Farmaceutici S.p.A. is the current owner and assignee of each of the eight (8) patents listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Chiesi's Kengreal®, including the patents in suit. The patents in suit were previously owned by The Medicines Company, on assignment from the inventors, some of who were employees of The

Medicines Company. Upon information and belief, The Medicines Company is a corporation having its principal place of business in Parsippany, New Jersey. Upon information and belief, one or more of the inventors of the patents in suit are located in Parsippany, New Jersey.

6. Upon information and belief, Gland is a corporation organized and existing under the laws of India, having a principal place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal Medchal-Malkajgiri District Hyderabad 500043, Telangana, India.

7. Upon information and belief, Gland is in the business of, among other things, the development, manufacturing, importation, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey. Gland's website states that Gland is "a global player with presence in about 90 countries in five continents," with "world-class manufacturing facilities accepted by global regulatory agencies including USFDA (USA)."[1] Gland's website further indicates that, in the U.S., it has 53 Abbreviated New Drug Applications (ANDAs) approved, 100 under review, and 71 under development.[2]

8. Upon information and belief, Gland derives substantial revenue from the sale of generic pharmaceutical products throughout the United States, including in New Jersey.

9. Upon information and belief, Gland is the current owner of ANDA No. 213551 ("Gland's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of generic cangrelor ("Gland's ANDA Product") throughout the United States, including in New Jersey, before the expiration of the '208 patent, the '052 patent, the '448 patent, the '921 patent, the '575 patent, the '265 patent, and the '780 patent. Upon

[1] About Us, http://www.glandpharma.com/about.html (last visited Dec. 3, 2019).

[2] Business Development, http://www.glandpharma.com/licensing.html (last visited Dec. 3, 2019).

information and belief, Gland's ANDA included a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A) ("paragraph IV certification") to the '208 patent, the '052 patent, the '448 patent, the '921 patent, the '575 patent, the '265 patent, and the '780 patent.

10. Upon information and belief, if Gland's ANDA receives final approval, Gland's ANDA Product will be manufactured, offered for sale, sold, distributed, and/or used by Gland in New Jersey; prescribed by physicians practicing in New Jersey; and/or administered to patients in New Jersey.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Gland at least because, upon information and belief: (i) Gland manufactures generic pharmaceutical products that are imported, distributed, and sold throughout the United States—including in New Jersey—and, thus, avails itself of the privileges and benefits of the laws and commerce of the United States, including New Jersey;[3] (ii) Gland regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, thereby demonstrating that Gland has continuous and systematic contacts with New Jersey; (iii) Gland has previously submitted to the jurisdiction of this Court and has availed itself of New Jersey's legal protections in at least four prior

[3] *See* Gland Pharma Ltd.'s Answer ¶ 13, *Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed May 15, 2013), ECF No. 241 (admitting that Gland "manufactures products that are sold throughout the United States, including in New Jersey"); Gland Pharma Ltd.'s Answer ¶ 4, *Medicure Int'l., Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed November 16, 2018), ECF No. 13 (admitting that Gland "develops, manufactures and/or distributes generic pharmaceutical products, and that certain generic pharmaceutical products developed, manufactured and/or distributed by Gland are ultimately sold in the United States, including in New Jersey.").

litigations;[4] and (iv) Gland has previously invoked this Court's jurisdiction by asserting counterclaims in at least three prior litigations.[5]

13. This Court has personal jurisdiction over Gland at least because, upon information and belief, if Gland's ANDA receives final approval, Gland's ANDA Product will be manufactured, offered for sale, sold, distributed, and/or used by Gland in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

14. Under 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 213551 with paragraph IV certification to the '208 patent, the '052 patent, the '448 patent, the '921 patent, the '575 patent, the '265 patent, and the '780 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the the '208 patent, the '052 patent, the '448 patent, the '921 patent, the '575 patent, the '265 patent, and/or the '780 patent is itself an act of infringement.

15. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) at least because, as set forth above, Gland is subject to personal jurisdiction in this Court and has committed and will commit acts of infringement.

16. Federal venue rules do not restrict the locations in which alien corporations, like Gland, may be sued. *In re HTC Corp.*, 889 F.3d 1349, 1354–61 (Fed. Cir. 2018) (citing *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *Brunette Mach. Works,*

[4] *See Novartis Pharma Corp. v. Gland Pharma Ltd.*, No. 14-1841 (D.N.J. filed Mar. 21, 2014); *Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharma Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012); *Medicure Int'l., Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed November 16, 2018).

[5] *See Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharma Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012); *Medicure Int'l., Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed November 16, 2018).

Ltd. v. Kockum Indus., Inc., 406 U.S. 706 (1972); *In re Hohorst*, 150 U.S. 653 (1893)). For that reason, venue is proper in this Court.

FACTS AS TO ALL COUNTS

17. Chiesi's Kengreal® is sold and marketed under NDA No. 204958, which was approved by FDA as a New Chemical Entity (NCE) on June 22, 2015.

18. Kengreal® is supplied as single-use 10 mL vial containing 50 mg Kengreal® as a lyophilized powder for reconstitution. Cangrelor, the active ingredient in Kengreal®, is a $P2Y_{12}$ platelet inhibitor indicated as an adjunct to percutaneous myocardial infarction (PCI) for reducing the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients in who have not been treated with a $P2Y_{12}$ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.

19. NDA No. 204958 pertains to Kengreal®'s 50 mg/vial presentation.

20. Kengreal®'s recommended dosage is 30 mcg/kg administered through intravenous (IV) bolus prior to percutaneous coronary intervention (PCI) followed immediately by a 4 mcg/kg/min intravenous (IV) infusion for at least 2 hours or the duration of the procedure, whichever is longer. Kengreal®'s prescribing information also recommends that in order to maintain platelet inhibition after discontinuation of Kengreal® infusion, an oral $P2Y_{12}$ platelet inhibitor should be administered.

21. FDA's publication, the Orange Book, lists eight (8) patents as covering Chiesi's Kengreal®: (1) U.S. Patent No. 10,039,780 ("the '780 patent"); (2) U.S. Patent No. 6,130,208 ("the '208 patent"); (3) U.S. Patent No. 8,680,052 ("the '052 patent"); (4) U.S. Patent No. 9,295,687 ("the '687 patent"); (5) U.S. Patent No. 9,427,448 ("the '448 patent"); (6) U.S. Patent No. 9,439,921 ("the '921 patent"); (7) U.S. Patent No. 9,700,575 ("the '575 patent"); and (8) U.S. Patent No. 9,925,265 ("the '265 patent"), (collectively, "Orange Book patents").

22. Gland sent a letter addressed to Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. dated August 19, 2019, purportedly pursuant to § 505(j)(2)(B)(iv) of the FD&C Act, 21 U.S.C. § 355(j)(2)(B)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations, regarding Gland's ANDA (the "First Notice Letter"). The First Notice Letter concerned the '687 patent.

23. Chiesi filed a patent infringement suit against Gland with respect to the '687 patent on September 30, 2019 (*Chiesi USA, Inc. et al v. Gland Pharma Ltd.*, Civil Action No. 2:19-cv-18565-MCA-MAH).

24. Gland sent a second letter addressed to Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. dated October 25, 2019, purportedly pursuant to § 505(j)(2)(B)(iv) of the FD&C Act, 21 U.S.C. § 355(j)(2)(B)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations, regarding Gland's ANDA (the "Second Notice Letter").

25. The Second Notice Letter states that Gland's ANDA has been submitted under § 505(j) of the FDCA, with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of a lyophilized formulation containing 50 mg/vial of cangrelor for injection, before the expiration dates of the patents in suit: the '208 patent, the '052 patent, the '448 patent, the '921 patent, the '575 patent, the '265 patent, and the '780 patent. The patents in suit are seven (7) of the eight (8) patents listed in FDA's Orange Book as covering Kengreal®.

26. Upon information and belief, Gland's ANDA was submitted under § 505(j)(2) of the FDCA with certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '208, '052, '448, '921,'575,'265, and '780 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Gland's ANDA Product.

27. Upon information and belief, the prescribing information for Gland's ANDA Product will have the same Indications and Usage as Kengreal®.

28. Upon information and belief, the prescribing information for Gland's ANDA Product will recommend the same Dosage and Administration as Kengreal®.

29. Upon information and belief, administration of Gland's ANDA Product, will be used to inhibit platelet aggregation in a patient in need thereof.

30. The '208 patent, titled "Formulation Containing a Nucleotide Analogue," was duly and legally issued by the U.S. Patent and Trademark Office on October, 10, 2000, to AstraZeneca UK Limited on assignment from inventor Joanne Broadhead. Chiesi Farmaceutici S.p.A. is the current owner and assignee of the '208 patent. The '208 patent is the National Stage Entry of PCT/SE98/01287, which was filed on June 29, 1998.

31. The '052 patent, titled "Methods of Treating, Reducing the Incidence of, and/or Preventing Ischemic Events," was duly and legally issued by the U.S. Patent and Trademark Office on March 25, 2014, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell, Simona Skerjanec, Jayne Prats, and David J. Schneider. Subsequently, The Medicines Company assigned the '052 patent to Chiesi Farmaceutici S.p.A.

32. The '448 patent, titled "Methods of Treating, Reducing the Incidence of, and/or Preventing Ischemic Events," was duly and legally issued by the U.S. Patent and Trademark Office on August 30, 2016, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell, Simona Skerjanec, and Jayne Prats. Subsequently, The Medicines Company assigned the '448 patent to Chiesi Farmaceutici S.p.A.

33. The '921 patent, titled "Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same," was duly and legally issued by the

U.S. Patent and Trademark Office on September 13, 2016, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the '921 patent to Chiesi Farmaceutici S.p.A.

34. The '575 patent, titled "Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same," was duly and legally issued by the U.S. Patent and Trademark Office on July 11, 2017, to Chiesi Farmaceutici S.p.A. on assignment from The Medicines Company and inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram.

35. The '265 patent, titled "Methods of Treating or Preventing Stent Thrombosis," was duly and legally issued by the U.S. Patent and Trademark Office on March 27, 2018, to Chiesi Farmaceutici S.p.A. on assignment from The Medicines Company and inventors Clive Arthur Arculus-Meanwell and Simona Skerjanec.

36. The '780 patent, titled "Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same," was duly and legally issued by the U.S. Patent and Trademark Office on August 7, 2018, to Chiesi Farmaceutici S.p.A. on assignment from The Medicines Company and inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram.

37. Any final approval of Gland's ANDA shall be effective no earlier than December 22, 2022. *See* 21 U.S.C. § 355(c)(3)(E)(ii).

38. As indicated in FDA's Orange Book, the patent expiration for the '780 patent is July 10, 2035; the patent expiration for the '208 patent is June 29, 2023; the patent expiration for the '052 patent is March 09, 2033; the patent expiration for the '448 patent is November 10,

2030; the patent expiration for the ’921 patent is July 10, 2035; the patent expiration for the ’575 patent is July 10, 2035; and the patent expiration for the ’265 patent is May 13, 2029.

FIRST COUNT
(Gland’s Infringement of the ’208 Patent)

39. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

40. Upon information and belief, Gland prepared Gland’s ANDA.

41. Upon information and belief, Gland submitted Gland’s ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland’s ANDA Product prior to the expiration of the patents in suit. Upon information and belief, Gland’s ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

42. Upon information and belief, Gland’s ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

43. Upon information and belief, Gland submitted Gland’s ANDA with a paragraph IV certification to the ’208 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland’s ANDA Product before the expiration of the ’208 patent.

44. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a “detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or

will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

45. Upon information and belief, as of the date of the Second Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

46. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the Second Notice Letter to Chiesi USA Inc. at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518; and another copy of the Second Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy.

47. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '208 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '208 patent is itself an act of infringement of the '208 patent.

48. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

49. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more of the '208 patent's claims under 35 U.S.C. § 271.

50. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '208 patent under 35 U.S.C. § 271.

51. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

52. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Gland's Infringement of the '052 Patent)

53. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

54. Upon information and belief, Gland prepared Gland's ANDA.

55. Upon information and belief, Gland submitted Gland's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the patents in suit. Upon information and belief, Gland's ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

56. Upon information and belief, Gland's ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

57. Upon information and belief, Gland submitted Gland's ANDA with a paragraph IV certification to the '052 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '052 patent.

58. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

59. Upon information and belief, as of the date of the Second Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

60. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the Second Notice Letter to Chiesi USA Inc. at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518; and another copy of the Second Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy.

61. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '052 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '052 patent is itself an act of infringement of the '052 patent.

62. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

63. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more of the '052 patent's claims under 35 U.S.C. § 271.

64. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '052 patent under 35 U.S.C. § 271.

65. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

66. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Gland's Infringement of the '448 Patent)

67. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

68. Upon information and belief, Gland prepared Gland's ANDA.

69. Upon information and belief, Gland submitted Gland's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the patents in suit.

Upon information and belief, Gland's ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

70. Upon information and belief, Gland's ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

71. Upon information and belief, Gland submitted Gland's ANDA with a paragraph IV certification to the '448 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '448 patent.

72. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

73. Upon information and belief, as of the date of the Second Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

74. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the Second Notice Letter to Chiesi USA Inc. at 1255

Crescent Green Drive, Suite 250, Cary, North Carolina 27518; and another copy of the Second Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy.

75. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '448 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '448 patent is itself an act of infringement of the '448 patent.

76. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

77. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more of the '448 patent's claims under 35 U.S.C. § 271.

78. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '448 patent under 35 U.S.C. § 271.

79. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

80. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Gland's Infringement of the '921 Patent)

81. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

82. Upon information and belief, Gland prepared Gland's ANDA.

83. Upon information and belief, Gland submitted Gland's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the patents in suit. Upon information and belief, Gland's ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

84. Upon information and belief, Gland's ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

85. Upon information and belief, Gland submitted Gland's ANDA with a paragraph IV certification to the '921 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '921 patent.

86. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or

each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

87. Upon information and belief, as of the date of the Second Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

88. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the Second Notice Letter to Chiesi USA Inc. at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518; and another copy of the Second Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy.

89. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '921 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '921 patent is itself an act of infringement of the '921 patent.

90. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

91. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more of the '921 patent's claims under 35 U.S.C. § 271.

92. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '921 patent under 35 U.S.C. § 271.

93. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

94. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Gland's Infringement of the '575 Patent)

95. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

96. Upon information and belief, Gland prepared Gland's ANDA.

97. Upon information and belief, Gland submitted Gland's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the patents in suit. Upon information and belief, Gland's ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

98. Upon information and belief, Gland's ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

99. Upon information and belief, Gland submitted Gland's ANDA with a paragraph IV certification to the '575 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '575 patent.

100. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and

legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

101. Upon information and belief, as of the date of the Second Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

102. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the Second Notice Letter to Chiesi USA Inc. at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518; and another copy of the Second Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy.

103. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '575 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '575 patent is itself an act of infringement of the '575 patent.

104. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

105. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's

ANDA Product would infringe, directly and/or indirectly, one or more of the '575 patent's claims under 35 U.S.C. § 271.

106. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '575 patent under 35 U.S.C. § 271.

107. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

108. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

SIXTH COUNT
(Gland's Infringement of the '265 Patent)

109. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

110. Upon information and belief, Gland prepared Gland's ANDA.

111. Upon information and belief, Gland submitted Gland's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the patents in suit. Upon information and belief, Gland's ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

112. Upon information and belief, Gland's ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

113. Upon information and belief, Gland submitted Gland's ANDA with a paragraph IV certification to the '265 patent for the purpose of obtaining FDA approval to engage in the

commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '265 patent.

114. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

115. Upon information and belief, as of the date of the Second Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

116. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the Second Notice Letter to Chiesi USA Inc. at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518; and another copy of the Second Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy.

117. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '265 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '265 patent is itself an act of infringement of the '265 patent.

118. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

119. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more of the '265 patent's claims under 35 U.S.C. § 271.

120. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '265 patent under 35 U.S.C. § 271.

121. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

122. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Gland's Infringement of the '780 Patent)

123. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

124. Upon information and belief, Gland prepared Gland's ANDA.

125. Upon information and belief, Gland submitted Gland's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the patents in suit.

Upon information and belief, Gland's ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

126. Upon information and belief, Gland's ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

127. Upon information and belief, Gland submitted Gland's ANDA with a paragraph IV certification to the '780 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '780 patent.

128. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

129. Upon information and belief, as of the date of the Second Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

130. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the Second Notice Letter to Chiesi USA Inc. at 1255

Crescent Green Drive, Suite 250, Cary, North Carolina 27518; and another copy of the Second Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy.

131. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '780 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '780 patent is itself an act of infringement of the '780 patent.

132. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

133. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more of the '780 patent's claims under 35 U.S.C. § 271.

134. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '780 patent under 35 U.S.C. § 271.

135. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

136. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment declaring that the '208 patent is valid and enforceable;

(B) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the ’208 patent by submitting to FDA Gland’s ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland’s ANDA Product before the expiration of the ’208 patent;

(C) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland’s ANDA Product before the expiration of the ’208 patent (including any regulatory extension), would directly and/or indirectly infringe the ’208 patent;

(D) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland’s ANDA shall be no earlier than the date on which the ’208 patent expires (including any regulatory extension);

(E) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland’s ANDA Product until the expiration of the ’208 patent (including any regulatory extension);

(F) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland’s ANDA, prior to the expiration of the ’208 patent (including any regulatory extension);

(G) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '208 patent is willful and awarding Chiesi enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '208 patent (including any regulatory extension);

(H) A judgment declaring that the '052 patent is valid and enforceable;

(I) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '052 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the '052 patent;

(J) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product before the expiration of the '052 patent (including any regulatory extension), would directly and/or indirectly infringe the '052 patent;

(K) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '052 patent expires (including any regulatory extension);

(L) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the

United States of Gland's ANDA Product until the expiration of the '052 patent (including any regulatory extension);

(M) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '052 patent (including any regulatory extension);

(N) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '052 patent is willful and awarding Chiesi enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '052 patent (including any regulatory extension);

(O) A judgment declaring that the '448 patent is valid and enforceable;

(P) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '448 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the '448 patent;

(Q) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product before the expiration of the '448 patent (including any regulatory extension), would directly and/or indirectly infringe the '448 patent;

(R) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '448 patent expires (including any regulatory extension);

(S) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until the expiration of the '448 patent (including any regulatory extension);

(T) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '448 patent (including any regulatory extension);

(U) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '448 patent is willful and awarding Chiesi enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '448 patent (including any regulatory extension);

(V) A judgment declaring that the '921 patent is valid and enforceable;

(W) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '921 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the

purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the '921 patent;

(X) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product before the expiration of the '921 patent (including any regulatory extension), would directly and/or indirectly infringe the '921 patent;

(Y) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '921 patent expires (including any regulatory extension);

(Z) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until the expiration of the '921 patent (including any regulatory extension);

(AA) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '921 patent (including any regulatory extension);

(BB) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '921 patent is willful and awarding Chiesi enhanced damages if

Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '921 patent (including any regulatory extension);

(CC) A judgment declaring that the '575 patent is valid and enforceable;

(DD) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '575 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the '575 patent;

(EE) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product before the expiration of the '575 patent (including any regulatory extension), would directly and/or indirectly infringe the '575 patent;

(FF) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '575 patent expires (including any regulatory extension);

(GG) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until the expiration of the '575 patent (including any regulatory extension);

(HH) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '575 patent (including any regulatory extension);

(II) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '575 patent is willful and awarding Chiesi enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '575 patent (including any regulatory extension);

(JJ) A judgment declaring that the '265 patent is valid and enforceable;

(KK) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '265 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the '265 patent;

(LL) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product before the expiration of the '265 patent (including any regulatory extension), would directly and/or indirectly infringe the '265 patent;

(MM) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '265 patent expires (including any regulatory extension);

(NN) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until the expiration of the '265 patent (including any regulatory extension);

(OO) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '265 patent (including any regulatory extension);

(PP) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '265 patent is willful and awarding Chiesi enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '265 patent (including any regulatory extension);

(QQ) A judgment declaring that the '780 patent is valid and enforceable;

(RR) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '780 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the '780 patent;

(SS) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or

importation into the United States of Gland's ANDA Product before the expiration of the '780 patent (including any regulatory extension), would directly and/or indirectly infringe the '780 patent;

(TT) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '780 patent expires (including any regulatory extension);

(UU) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until the expiration of the '780 patent (including any regulatory extension);

(VV) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '780 patent (including any regulatory extension);

(WW) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '780 patent is willful and awarding Chiesi enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '780 patent (including any regulatory extension);

(XX) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Chiesi its attorneys' fees and costs;

(YY) Such other and further relief as this Court may deem just and proper.

Dated: December 9, 2019

Respectfully submitted,

By: /s/ Charles H. Chevalier

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